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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,292	01/02/2004	Mark A. Hoffman	CRNC.107055	1596

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SHOOK, HARDY & BACON L.L.P.
(Cerner Corporation)
Intellectual Property Department
2555 GRAND BOULEVARD
KANSAS CITY, MO 64108-2613

EXAMINER	
SKOWRONEK, KARLHEINZ R	
ART UNIT	PAPER NUMBER
1631	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/751,292	HOFFMAN ET AL.	
	Examiner	Art Unit	
	KARLHEINZ R. SKOWRONEK	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06 July 2010* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06 July 2010 has been entered.

Claim Status

Claims 32-52 are pending.

Claims 1-31 are cancelled.

Claims 32-52 have been examined.

Claims 32-52 are rejected.

Priority

This application, filed on 02 January 2004, is a continuation in part of application No. 09/981248 which was filed on 16 October 2001 and claims priority to Provisional application No. 60/509023, filed on 06 October 2003.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 06 July 2010 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36 and 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36 and 50 recites the limitation "the instructions " in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claims 36 and 50 are unclear with respect to the claim further limitations of the method. The metes and bounds of the claim are rendered indefinite by the lack of clarity. Claims 36 and 50 are directed to further embodiments of the methods of claims 32 and 49, respectively. Claims 36 and 50 recite the limitations of instructions for the method stored on a computer storage medium. Claims appear to be directed to a product It is unclear what step of the process applicant intends to limit.

Claim Rejections - 35 USC § 101

The rejection of claims 32-40 and 49-52 is with drawn in view of the amendment to the claims.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 36 and 50 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 36 and 50 are directed to

embodiments of a method wherein the instructions for the method are embodied on one or more computer storage media. The claims are rejected under 35 USC 101 as non-statutory as being directed to both a process and an apparatus. Thus the claims are directed to neither a machine nor a process, but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only.

Claims 36 and 50 are directed to computer storage media. A review of the specification does not show a definition of computer readable media such that excludes an embodiment that is information in a signal. As such an embodiment of the claims read on non-statutory subject matter (In re Nuijten 84 USPQ2d 1495 (2007)). The specification, as originally filed, recites at p. 6, ¶ [0022], "By way of example, and not limitation, computer readable media may comprise computer storage media and communication media. Computer storage media includes both volatile and nonvolatile, removable and non-removable media implemented in any method or technology for storage of information, such as computer readable instructions, data structures, program modules or other data. Computer storage media includes, but is not limited to, RAM, ROM, EEPROM, flash memory or other memory technology, CD-ROM, digital versatile disks (DVD), or other optical disk storage, magnetic cassettes, magnetic tape, magnetic disk storage, or other magnetic storage devices, **or any other medium** which can be used to store the desired information and which can be accessed by server 22" (emphasis added by examiner). The exemplary description of computer storage media in the specification is broad so as to also encompass communication media. Thus,

claims 36 and 50 are appropriately interpreted to encompass non-statutory embodiments, such as carrier waves which transiently store information. The specification at [0022] also described various “non-transitory computer storage media” which are statutory.

Claims 36 and 50 are directed to instructions on a computer storage media. The term “instructions" is broadly interpreted to encompass both functional and nonfunctional descriptive material. When nonfunctional descriptive material is recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, it is not statutory since no requisite functionality is present to satisfy the practical application requirement.

Response to Arguments

Applicant's arguments filed 06 July 2010 have been fully considered but they are not persuasive. Applicant argues claims 36 and 50 are directed to computer executable instructions embedded on computer storage media and are thus statutory (remarks, 6 July 2010, p. 10-11). The argument is not persuasive. Claims 36 and 50 recite, “wherein the instructions for the method are embodied on one or more computer storage media”. First, the instructions stored are not explicitly machine executable instructions. The recitation of "the instructions" encompass any type of instruction. As a result the instructions are not functionally interrelated with the media and are not statutory. Second, as discussed above the description of computer media is not defined by the specification to be limited to only statutory embodiments. Rather, the specification describes computer storage media with such breadth so as to encompass

"**any other medium** which can be used to store the desired information" (specification, [0022], emphasis added by examiner).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following rejection is necessitated by amendment of the claims.

Claim 32-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akers et al. (US PAT 6,112,182), in view of Denton et al. (WO 2001/01218), and in view of Harris et al. (IDS 4/12/2004, NPL reference 1) in view of Pathak et al.

The claims are directed to a method (claims 32-40) in which a prescription for a patient is received from a clinician; determining if the prescribed agent or event is correlated with a gene; querying a database to determine if the patient has genetic results consistent with the correlated gene; if the genetic test results do not exist, obtain the route of inheritance for the gene; query a database to identify any family members with genetic test results with the route of inheritance; use the genetic results of the identified family members to calculate the probability that the patient has a gene mutation; report the probability that the patient has a gene mutation.

Akers et al. shows a method and system in which an electronic order for a clinical agent is received (col. 4, line 37-40). Akers et al. shows that the order is automatically checked for adverse reactions (col. 4, line 49-55). Akers et al. shows that a table is searched to identify conflicts with the requested drug. Akers et al. shows that if a conflict is detected an alert is presented (col. 4, line 58-60).

Akers et al. does not show that the conflicts correlate genetic findings associated with the clinical agent or drug.

Denton et al. shows that mutations in genes effects how an individual responds to a clinical agent (p. 3). Denton shows the mutations in a gene can produce atypical events. Denton et al. shows the determination of whether a mutation results in an

atypical event (p. 48). Denton et al. shows that the mode of inheritance is obtained by showing that for any given patient, the haplotypes for the gene is checked for a Mendelian inheritance pattern (p. 16-17). Denton et al. shows the correlation mutations in genes with a person's response to a particular drug in a database, which reads on a table (p. 70). Denton et al. shows that associating genes and their haplotypes with responses to particular drugs, one can find correlations that predict an individual's response (p. 6-7). Denton et al. shows a result of the drug gene association is that the number of adverse reactions is decreased (p. 5-6). Denton et al. shows the database includes genetic information of the patient and family members (p. 72). Denton et al. shows the benefit of correlating drug response with gene mutations is that the best available drug and/or dose for a patient can be prescribed immediately rather than relying on a trial and error approach to find the optimal drug (p. 6).

Akers et al. in view of Denton et al. does not show the generation of likelihood that a person has a mutation.

Harris et al. shows that a mode of inheritance is determined for a gene (p. 37 , col. 2). Harris et al. shows that a server or computer is utilized to identify an individual in the family related to the person within the mode of inheritance of the selected gene using a belief net (figure 6). Harris et al. shows that the application of belief nets to pedigree data advantageously provides a method that works for any family with any single-gene inherited defect and that information outside the pedigree can be incorporated with out disrupting the structure of the underlying family structure (p. 40, col. 1).

Pathak et al. shows that the likelihood or probability that a person has a mutation in a gene can be determined automatically (p. 164, col. 1). The system analyzes the data and produces a probability of the presence of a mutation. The input of case data as depicted in fig. 1 conceptually demonstrates data that is stored and utilized by the system, thereby reading on the limitation of a database. Consistent with the limitation of a database is the blackboard (p.165, col. 2, para. 1), a global data structure. Pathak et al. teach the input as a set of objects each having the attributes name, sex, parents, siblings, spouse, children, loci (p.165, col. 2, para. 1). The attribute *loci*, as Pathak et al. teach, is a set of alleles in the genome reading on the limitation of genetic test results (p.165, col. 2, para. 1). Pathak et al. teach the use of rule sets to define queries of the case data to identify the route of inheritance based on familial relationships as well as to utilize the loci information to calculate a probability of an allele's presence (p.165, col. 2, para. 2 and p. 166, col. 2, #8). Pathak et al. shows genetic risks influence medical decisions (p. 169, col. 2). Regarding claim 34, Pathak et al. teach knowledge sources concerned with allele inheritance relations within the pedigree, reading on mode of inheritance or genetically related family members (p. 165, col. 2, "allele flow"). Regarding claim 35, Pathak et al. teach calculating the likelihood the individual has a mutated form of the gene using the genetic markers (alleles) of at least one family member (p. 166, col. 2, "possible–explanations" and "Bayesian-analysis"). Regarding claim 36, Pathak et al. teach a computer readable media comprising the instructions for the method (p. 169, col. 2, para 2, "software"). Regarding claim 39, Pathak et al. teach the example of x-linked mode of inheritance (p. 167, col. 1, "X-linked"). Regarding

claims 33 and 40 Pathak et al. teach that all a user must do is provide the system with the relevant data (p. 169, col. 1, last three lines). It is common for an individual's medical information to exist in electronic form and comprise medical data of related family members. Therefore, the teaching of providing the system with the relevant data is viewed to read on the limitations of electronic records from a comprehensive healthcare database. Pathak et al. shows the system provides the advantage of streamlining the computation of genetic risk (p. 169, col. 2)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method and system of Akers et al. managing patient care by identifying conflicts in treatments with the identification of correlations between gene mutations and treatment responses of Denton et al. because Denton et al. shows the benefit of correlating drug response with gene mutations is that the best available drug and/or dose for a patient can be prescribed immediately rather than relying on a trial and error approach to find the optimal drug. It would have been further obvious to modify the method and system of Akers et al. in view of Denton et al. with the automatic determination of genetic likelihoods of Pathak et al. because Pathak et al. shows the system provides the advantage of streamlining the computation of genetic risk. It would have been further obvious to one of ordinary skill in the art at the time of invention to modify the method and system of Akers et al. in view of Denton et al. in view of Pathak et al. with the utilization of a server or computer to identify a family member of the person within the traversal pattern specified by the selected mode of inheritance of Harris et al. because Harris et al. shows that the application of belief nets to pedigree

data advantageously provides a method that works for any family with any single-gene inherited defect and that information outside the pedigree can be incorporated with out disrupting the structure of the underlying family structure.

Response to Arguments

Applicant's arguments filed 12 November 2009 have been fully considered but they are not persuasive. Applicant argues Akers et al. in view of Denton et al. in view of Pathak fail to show the steps of obtaining a mode of inheritance and determining a member of the family of the person within the pattern of traversal specified by the mode of inheritance. The argument is not persuasive. Harris et al. shows that a mode of inheritance is selected and a member of the family of the person is identified within the traversal pattern specified by the mode of inheritance.

The following rejection is modified from the previous action.

Claims 41-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akers et al. (US PAT 6,112,182), in view of Denton et al. (WO 2001/01218), in view of Pathak et al., in view of Harris et al., in view of Wijker et al. (Hum. Mol. Gen., Vol. 5, No.1, p. 151-154, 1996), and in view of Lathrop et al. (PNAS, Vol. 81, p. 3443-3446, 1984).

The claims are directed to a method (claims 32-40 and 49-52) and system (claims 41-48) in which a prescription for a patient is received from a clinician; determining if the prescribed agent or event is correlated with a gene; querying a database to determine if the patient has genetic results consistent with the correlated

gene; if the genetic test results do not exist, obtain the route of inheritance for the gene; query a database to identify any family members with genetic test results with the route of inheritance; use the genetic results of the identified family members to calculate the probability that the patient has a gene mutation; report the probability that the patient has a gene mutation.

Akers et al. shows a method and system in which an electronic order for a clinical agent is received (col. 4, line 37-40). Akers et al. shows that the order is automatically checked for adverse reactions (col. 4, line 49-55). Akers et al. shows that a table is searched to identify conflicts with the requested drug. Akers et al. shows that if a conflict is detected an alert is presented (col. 4, line 58-60).

Akers et al. does not show that the conflicts correlate genetic findings associated with the clinical agent or drug.

Denton et al. shows that mutations in genes effects how an individual responds to a clinical agent (p. 3). Denton shows the mutations in a gene can produce atypical events. Denton et al. shows the determination of whether a mutation results in an atypical event (p. 48) Denton et al. shows the correlation mutations in genes with a person's response to a particular drug in a database, which reads on a table (p. 70). Denton et al. shows the database includes genetic information of the patient and family members (p. 72). Denton et al. shows the benefit of correlating drug response with gene mutations is that the best available drug and/or dose for a patient can be prescribed immediately rather than relying on a trial and error approach to find the optimal drug (p. 6).

Akers et al. in view of Denton et al. do not show the generation of likelihood that a person has a mutation.

Harris et al. shows that a mode of inheritance is determined for a gene (p. 37 , col. 2). Harris et al. shows that a server or computer is utilized to identify an individual in the family related to the person within the mode of inheritance of the selected gene using a belief net (figure 6). Harris et al. shows that the application of belief nets to pedigree data advantageously provides a method that works for any family with any single-gene inherited defect and that information outside the pedigree can be incorporated with out disrupting the structure of the underlying family structure (p. 40, col. 1).

Pathak et al. shows that the likelihood or probability that a person has a mutation in a gene can be determined automatically (p. 164, col. 1). The system analyzes the data and produces a probability of the presence of a mutation. The input of case data as depicted in fig. 1 conceptually demonstrates data that is stored and utilized by the system, thereby reading on the limitation of a database. Consistent with the limitation of a database is the blackboard (p.165, col. 2, para. 1), a global data structure. Pathak et al. teach the input as a set of objects each having the attributes name, sex, parents, siblings, spouse, children, loci (p.165, col. 2, para. 1). The attribute *loci*, as Pathak et al. teach, is a set of alleles in the genome reading on the limitation of genetic test results (p.165, col. 2, para. 1). Pathak et al. teach the use of rule sets to define queries of the case data to identify the route of inheritance based on familial relationships as well as to utilize the loci information to calculate a probability of an allele's presence (p.165, col. 2,

para. 2 and p. 166, col. 2, #8). Pathak et al. shows genetic risks influence medical decisions (p. 169, col. 2). Regarding claim 43, Pathak et al. teach knowledge sources concerned with allele inheritance relations with in the pedigree, reading on mode of inheritance or genetically related family members (p. 165, col. 2, "allele flow"). Regarding claim 44, Pathak et al. teach calculating the likelihood the individual has a mutated form of the gene using the genetic markers (alleles) of at least one family member (p. 166, col. 2, "possible–explanations" and "Bayesian-analysis"). Pathak et al. teach a computer readable media comprising the instructions for the method (p. 169, col. 2, para 2, "software"). Regarding claim 48, Pathak et al. teach the example of x-linked mode of inheritance (p. 167, col. 1, "X-linked"). Regarding claims 42 and 45, Pathak et al. teach that all a user must do is provide the system with the relevant data (p. 169, col. 1, last three lines). It is common for an individual's medical information to exist in electronic form and comprise medical data of related family members. Therefore, the teaching of providing the system with the relevant data is viewed to read on the limitations of electronic records from a comprehensive healthcare database. Pathak et al. shows the system provides the advantage of streamlining the computation of genetic risk (p. 169, col. 2).

Akers et al. in view of Denton et al. in view of Pathak et al. do not show searching a table to determine a maximum distance from a gene to find genetic findings of linked genes for the person.

Wijker et al. shows a method in which multilocus linkage analysis is applied to identify location of the gene for PPND to chromosome 17q21 (abstract). Wijker et al.

shows a table that is searched to determine the maximum distance from the gene to search for linked genes (table 1). Wijker et al. shows that from the search of the table, markers linked to the gene for PPND are found to exist within a maximum distance of 10 centimorgans (p. 153, col. 1).

Lathrop et al. shows an algorithm for multilocus linkage analysis. Lathrop et al. shows multilocus analysis substantially improves the efficiency of linkage analysis and accuracy of the inferred genetic map (p. 3444, col. 2). Lathrop et al. shows this allows the expression of the disease locus relative to selected test markers (3445, col. 1). Lathrop et al. suggests creating a database of markers (p. 3446, col. 2). Lathrop et al. shows that multilocus analysis has the further advantage of increased precision of the estimated location of the new locus on the genetic map (p. 3445, col. 1).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method and system of Akers et al. managing patient care by identifying conflicts in treatments with the identification of correlations between gene mutations and treatment responses of Denton et al. because Denton et al. shows the benefit of correlating drug response with gene mutations is that the best available drug and/or dose for a patient can be prescribed immediately rather than relying on a trial and error approach to find the optimal drug. It would have been further obvious at the time of invention to modify the method and system of Akers et al. in view of Denton et al. with the automatic determination of genetic likelihoods of Pathak et al. because Pathak et al. shows the system provides the advantage of streamlining the computation of genetic risk. It would have been further obvious to one of ordinary skill in the art at

the time of invention to modify the method and system of Akers et al. in view of Denton et al. in view of Pathak et al. with the utilization of a server or computer to identify a family member of the person within the traversal pattern specified by the selected mode of inheritance of Harris et al. because Harris et al. shows that the application of belief nets to pedigree data advantageously provides a method that works for any family with any single-gene inherited defect and that information outside the pedigree can be incorporated with out disrupting the structure of the underlying family structure. It would have been further obvious at the time of invention to modify the method and system of Akers et al. in view of Denton et al. in view of Pathak et al. and in view of Harris et al. with the table for determining the maximum distance to search for genes or markers linked to the gene of Wijker et al. because the technique of linkage analysis was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying linkage analysis to a method or device for identifying correlations between gene mutations and treatment responses that was ready for improvement and the results would have been predictable to one of ordinary skill in the art.

Response to Arguments

Applicant's arguments filed 06 July 2010 have been fully considered but they are not persuasive. Applicant argues Akers et al., in view of Denton et al., in view of Pathak et al., in view of Harris et al., in view of Wijker et al., and in view of Lathrop et al. fail to show the steps of obtaining a mode of inheritance and determining a member of the family of the person within the pattern of traversal specified by the mode of inheritance.

The argument is not persuasive. Harris et al. shows that a mode of inheritance is selected and a member of the family of the person is identified within the traversal pattern specified by the mode of inheritance.

The following rejection modified from the previous action.

Claim 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akers et al. (US PAT 6,112,182), in view of Denton et al. (WO 2001/01218), in view of Harris et al., in view of Pathak et al. and in view of Pratt et al. (Am. J. Hum. Genet., Vol. 66, p. 1153-1157, 2000).

The claims are directed to a method (claims 49-52) in which a prescription for a patient is received from a clinician; determining if the prescribed agent or event is correlated with a gene; querying a database to determine if the patient has genetic results consistent with the correlated gene; if the genetic test results do not exist, obtain the route of inheritance for the gene; query a database to identify any family members with genetic test results with the route of inheritance; use the genetic results of the identified family members to calculate the probability that the patient has a gene mutation; report the probability that the patient has a gene mutation.

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a table is searched to identify conflicts with the requested drug. Akers et al. shows that if a conflict is detected an alert is presented (col. 4, line 58-60).

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Akers et al. in view of Denton et al. does not show the generation of likelihood that a person has a mutation.

Harris et al. shows that a mode of inheritance is determined for a gene (p. 37 , col. 2). Harris et al. shows that a server or computer is utilized to identify an individual in the family related to the person within the mode of inheritance of the selected gene using a belief net (figure 6). Harris et al. shows that the application of belief nets to pedigree data advantageously provides a method that works for any family with any single-gene inherited defect and that information outside the pedigree can be

incorporated with out disrupting the structure of the underlying family structure (p. 40, col. 1).

Pathak et al. shows that the likelihood or probability that a person has a mutation in a gene can be determined automatically (p. 164, col. 1). The system analyzes the data and produces a probability of the presence of a mutation. The input of case data as depicted in fig. 1 conceptually demonstrates data that is stored and utilized by the system, thereby reading on the limitation of a database. Consistent with the limitation of a database is the blackboard (p.165, col. 2, para. 1), a global data structure. Pathak et al. teach the input as a set of objects each having the attributes name, sex, parents, siblings, spouse, children, loci (p.165, col. 2, para. 1). The attribute *loci*, as Pathak et al. teach, is a set of alleles in the genome reading on the limitation of genetic test results (p.165, col. 2, para. 1). Pathak et al. teach the use of rule sets to define queries of the case data to identify the route of inheritance based on familial relationships as well as to utilize the loci information to calculate a probability of an allele's presence (p.165, col. 2, para. 2 and p. 166, col. 2, #8). Pathak et al. shows genetic risks influence medical decisions (p. 169, col. 2). Pathak et al. teach knowledge sources concerned with allele inheritance relations with in the pedigree, reading on mode of inheritance or genetically related family members (p. 165, col. 2, "allele flow"). Pathak et al. teach calculating the likelihood the individual has a mutated form of the gene using the genetic markers (alleles) of at least one family member (p. 166, col. 2, "possible–explanations" and "Bayesian-analysis"). Pathak et al. teach a computer readable media comprising the instructions for the method (p. 169, col. 2, para 2, "software"). Pathak et al. teach the

example of x-linked mode of inheritance (p. 167, col. 1, "X-linked"). Pathak et al. teach that all a user must do is provide the system with the relevant data (p. 169, col. 1, last three lines). It is common for an individual's medical information to exist in electronic form and comprise medical data of related family members. Therefore, the teaching of providing the system with the relevant data is viewed to read on the limitations of electronic records from a comprehensive healthcare database. Pathak et al. shows the system provides the advantage of streamlining the computation of genetic risk (p. 169, col. 2)

Akers et al. in view of Denton et al. in view of Pathak et al. do not show calculating an inferred finding from Quantitative Trait Loci (QTL) analysis.

Pratt et al. shows the inference of a mutation at a locus by a combination of pedigree (family member association) analysis and QTL analysis (p. 1155, col. 2). Pratt et al. shows that QTL analysis has the benefit of the relative size of the component gives a measure of the magnitude of the effect of a detected locus (.p. 1153, col. 2).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method and system of Akers et al. managing patient care by identifying conflicts in treatments with the identification of correlations between gene mutations and treatment responses of Denton et al. because Denton et al. shows the benefit of correlating drug response with gene mutations is that the best available drug and/or dose for a patient can be prescribed immediately rather than relying on a trial and error approach to find the optimal drug. It would have been further obvious to modify the method and system of Akers et al. in view of Denton et al. with the automatic

determination of genetic likelihoods of Pathak et al. because Pathak et al. shows the system provides the advantage of streamlining the computation of genetic risk. It would have been further obvious to one of ordinary skill in the art at the time of invention to modify the method and system of Akers et al. in view of Denton et al. in view of Pathak et al. with the utilization of a server or computer to identify a family member of the person within the traversal pattern specified by the selected mode of inheritance of Harris et al. because Harris et al. shows that the application of belief nets to pedigree data advantageously provides a method that works for any family with any single-gene inherited defect and that information outside the pedigree can be incorporated with out disrupting the structure of the underlying family structure. It would have been further obvious to modify the method and system of Akers et al. in view of Denton et al. and the automatic determination of genetic likelihoods of Pathak et al. with the QTL analysis of Pratt et al. because Pratt et al. shows that QTL analysis has the benefit of the relative size of the component gives a measure of the magnitude of the effect of a detected locus.

Response to Arguments

Applicant's arguments filed 06 July 2010 have been fully considered but they are not persuasive. Applicant argues that Akers et al., in view of Denton et al., in view of Harris et al., in view of Pathak et al. and in view of Pratt et al. fail to show the steps of obtaining a mode of inheritance and determining a member of the family of the person within the pattern of traversal specified by the mode of inheritance. The argument is not persuasive. Harris et al. shows that a mode of inheritance is selected and a member of

the family of the person is identified within the traversal pattern specified by the mode of inheritance.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571)272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/KARLHEINZ R SKOWRONEK/
Primary Examiner, Art Unit 1631

25 August 2010